



A Clinical Evaluation of Daruharidra (*Berberis aristata* D.C.) in cases of Giardiasis

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Abstract

Daruharidra (*Berberis aristata* D.C.) has been described in ancient Ayurvedic texts for treatment of Jaundice, Skin diseases and abdominal diseases etc. Hence the present study was carried out in randomly selected cases of stool +ve Giardiasis. The stem and root of *Berberis aristata* (BA) was administered in capsules after drying in shade and rough grinding. Out of 268 cases with abdominal symptoms and ill health 69 were found +ve for Giardiasis only. These were treated with 1 gm BD of the *Berberis aristata* powder for 14 days. Ninety-five percent cases were found free of parasites in stool after treatment. The clinical, Stool microscopic and hematological profiles were studied. The haematological profiles of the patients were improved after 1 month and 1.5 month of treatment. There was significant improvement in clinical profile of patients treated with *Berberis aristata*. The demographic characteristics of patients were also studied but there was no any correlation between demographic details and infestation of *Giardia lamblia*.

Keywords: Giardiasis, *Berberis aristata*, Daruharidra, Grahani Roga, Jaundice, Liver disease

1. Introduction

Giardiasis is not only a problem of Indian subcontinent but presently it is recognised as a global problem. 12.5% of world population is suffering from *Giardia* infection¹. The manifestation of *Giardia* is so variable that inspite of large number of studies it is difficult to assess and correlate its clinical effects in man. It starts from asymptomatic condition to severe diarrhoea, malabsorption syndrome and liver necrosis. The effect of *Giardia* is also well documented for its allergy inducing effects in normal and immunocompromised patients treated with corticosteroids, suffering from renal failure and diabetes mellitus^{2,3}. In severely infected individuals symptoms like flatulence, nausea, epigastric discomfort, vomiting belching, anorexia, salivation chronic diarrhoea or constipation have been reported^{4,5}. Giardiasis is as old as the Indian civilization as it has been described in ancient Ayurvedic texts (Carak 2700-600 B.C.) as Grahani Roga. A lot of herbals have been prescribed for Grahani Roga in Ayurvedic texts. Although modern drugs viz; Metronidazole and Albendazole are quite effective in Giardiasis^{4,6} but at the same time they produce many side and toxic side effects⁷. The modern drugs also compromise the immune status of the patient while on the other hand the herbals cure the disease and also increase the immunity as well. Thus, Daruharidra was selected for this

study to verify the claim of Ayurveda for its use in treatment of Grahani Roga, jaundice and other liver diseases.

2. Materials and Methods

A placebo controlled double blind clinical trial was conducted to assess the effectiveness of BA in patients of Giardiasis. The stools of 268 subjects with mild to severe abdominal disturbances were examined for the presence of cysts and trophozoites of *Giardia lamblia* and other parasites. Among these stools of 49 cases were negative for presence of any parasite, ova and cyst, in 150 cases found multiple infection of *Giardia lamblia*, *Ascaris lumbricoides*, *Entamoeba histolytica*, *Enterobius vermicularis*, and *Escherichia* while 69 clearly positive cases were taken for study. They were initially divided into two groups (Group I and Group II).

Group I consisted of 46 adults patients and subdivided into Group Ia and Group Ib. Group Ia consisted of 31 adult patients, 12 males and 19 females with mean age of 45.3 ± 5.1 years and 53.1 ± 4.2 respectively. All the patients of Group Ia treated with BA in doses of 400 mg TDS orally for a period of 14 days by BA powder filled in gelatin capsules. The clinical profile, stool microscopic and haematological profiles were studied in the patients on pre-treatment day (0 day) and after treatment with BA on days 15, 30 and 45.

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Group Ib consisted of 15 patients 9 males and 6 females with mean age of 39.8 ± 3.7 years and 36.2 ± 4.2 years respectively. All 15 patients of Group Ib were administered with starch filled capsules in dosage schedule of 400 mg TDS p.o. for a period of 14 days. All the profile including clinical profile, stool microscopic profile and haematological profile was studied for their parameters before treatment day (0 day) and on 15, 30 and 45 days after treatment.

Group II consisted of 23 children and subdivided in Group IIa and IIb. Group IIa consisted of 13 malnourished children, 8 males and 5 females with mean age of 8.9 ± 2.1 years and 9.4 ± 1.7 years respectively. All the children of Group IIa presented with malabsorption syndrome with their protruded tummies and anemia with ill health as a prominent feature. The children were physically weak and less active in comparison to other children of their age group. BA powder filled in smaller gelatin capsules and administered in dosage schedule of 200mg TDS p.o. for a period of 14 days. The clinical profile, stool microscopic profile and haematological profiles were studied on 0 day (before treatment) and on 15, 30 and 45 days after treatment.

Group IIb consisted of 10 *Giardia* positive children, 5 males and 5 females with mean age of 7.5 ± 0.8 and 8.1 ± 1.4 years respectively. Group II b was treated with starch filled in smaller identical gelatin capsules in doses of 200 mg TDS p.o. for a period of 14 days. Clinical, stool microscopic profile and haematological profiles were studied on 0 day (before treatment) and on 15, 30 and 45 days after treatment.

Group Ib and IIb later served as Group Ic and IIc and were treated with BA powder in doses of 400mg, 200mg TDS p.o. respectively for a period of 14 days and conducted a cross over study due to ethical reasons. The clinical, stool microscopic profile and haematological profiles were studied on 0 day (before treatment) and on 15, 30 and 45 days after treatment.

The clinical profile was studied for different signs and symptoms profile of patients including diarrhoea, constipation, flatulence, belching, vomiting, anorexia, pyrexia, salivation, abdominal discomfort, nausea, foul smelling stool, abnormal consistency of stool and abnormal frequency of stools etc.

The stool microscopic profile was studied for presence of trophozoites and cysts of *Giardia lamblia*, mucus, pus cells, R.B.Cs, fat globules, undigested food particles, bacterial outgrowth etc.

The haematological profile was seen for hemoglobin gm%, Total Leukocyte Count (TLC), Differential Leukocyte Count (DLC) i.e., lymphocytes, polymorphs, monocytes and eosinophil etc. The findings of all the three profiles were observed on 0 day (before treatment) and post treatment days 15, 30, 45. Comparisons have been made with 0 day and placebo control groups to see the effectiveness of BA All the data were statistically analysed for its significance. The patients of all the groups were advised to take boiled cooled water during the period of study. The patients positive for multiple infections were treated with modern drugs for their disease.

3. Results

The results of Group I are summarized in (Table 1 to 3) for Group Ia and (Table 4 to 6) for Group Ib and (Table 7 to 9) for Group Ic. Group I consisted of 46 adults and sub divided into Group Ia and Group Ib. The results of Group II are summarized in (Table 10 to 12) for Group IIa and. (Table 13 to 15) for Group IIb and (Table 16 to 18) for Group IIc. Group II consisted of 46 adults and sub divided into Group Ha and Group IIb.

4. Discussion and Conclusion

Grahani Roga of Ayurveda appears to be very akin to Giardiasis and *Giardia* related malabsorption syndrome⁸. It has been treated by various herbal preparations and herbs since long. *Giardia*, considered to be a harmless parasite in man a few decades back has have been established to cause ill health and malabsorption syndrome in many people particularly in countries like India where reinfections are very common due to poor hygienic conditions and uncured water supply for human consumption. Repeated infections ultimately result in ill health while people with few infections may remain symptomless (asymptomatic)^{6,9,10}. The incidence of this disease did not show any correlation with sex, age, weight, food habit, religion and marital status, however, the bad sanitary conditions and poor hygiene show higher incidence.

The results of this study (Tables 1 to 3 and 10 to 12) show significant improvement in clinical profile, stool microscopic profile and blood microscopic profile. A significant increase in hemoglobin contents and decrease in eosinophil count was

Table 1. Group Ia. Effect of BA on Clinical profile (in%)

Signs and symptoms	0 days	15 day	30 day	45 day
Diarrhoea	68	10*	7*	0*
Abnl. freq. of stool	87	16*	7*	7*
Foul smelling stool	100	19*	16*	16*
Abnl. consist of stool	87	13*	7*	7*
Abd. discomfort	97	13*	10*	7*
Abnl. no. of stool	100	7*	0*	0*
Abnormal appetite	74	26**	10*	7*
Nausea	84	7*	10*	7*
Flatulence	97	19*	10*	10*
Vomiting	68	10*	0*	0*
Belching	74	10*	7*	7*
Belching	74	10*	7*	7*
Anorexia	74	10*	7*	10*
Salivation	65	10*	7*	7*
Constipation	29	7*	0*	0*

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control.

observed after 14 days treatment with BA. The observations were made on day 15, 30 and 45 in groups Ia and IIa and later Ic and IIc.

The results of placebo groups (Group Ib, Group IIb) shown in Tables 4 to 6 and Tables 13 to 15, There were insignificant changes occurred in all the parameters observed. Only three patients in placebo group Ib and one in placebo group IIb recovered spontaneously as their stools were clear from *Giardia* cysts and trophozoites. Thus the spontaneous recovery occurs in some cases of Giardiasis.

Group Ib, Group IIb later treated as Group Ic and Group IIc and BA treatment was done in similar way as in Group Ia and Group IIa as a cross over study for comparison with the same placebo control group. This clinical trial with BA was

Table 2. Group Ia. Effect of BA on Stool microscopic profile (in%)

Parasites & path. Cont.	0 days	15 day	30 day	45 day
G. Cysts	100	13*	10*	7*
G. Tropho.	23	0*	0*	0*
Mucus	94	19*	16*	16*
R.B.Cs	65	23**	16*	13*
Pus cells	68	16**	10*	7*
Fat globules	74	19**	7*	7*
U.F.P.	84	10*	7*	7*
Bacterial outgrowth	61	16**	10*	10*

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control group.

Table 3. Group Ia. Effect of BA on Haematological profile (in%)

Parameters	0 days Mean ± S.E.	15 day Mean ± S.E.	30 day Mean ± S.E.	45 day Mean ± S.E.
Haemoglobin	11.2 ± 0.3	12.7 ± 0.3**	13.5 ± 0.4*	14.7 ± 0.4*
Eosinophil	9.4 ± 0.3	6.1 ± 0.2**	4.3 ± 0.2*	3.2 ± 0.2*
Lymphocyte	32.1 ± 1.4	29.6 ± 1.3	31.5 ± 1.3	34.2 ± 1.3
Monocyte	0.5 ± 0.2	0.8 ± 0.2	1.0 ± 0.2	0.5 ± 0.2
Polymorph	62.7 ± 1.6	60.6 ± 1.3	63.2 ± 1.6	62.1 ± 1.4
T.L.C.	8215.0 ± 81.2	8302.3 ± 73.6	8134.1 ± 39.2	8206.2 ± 28.2

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control group.

Table 4. Group Ib. Effect of BA on Clinical profile (in%)

Signs and symptoms	0 days	15 day	30 day	45 day
Diarrhoea	47	47#	53#	53#
Abnl. freq. of stool	73	67#	67#	73#
Foul smelling stool	100	93#	87#	93#
Abnl. consist of stool	80	73#	67#	73#
Abd. discomfort	100	93#	87#	93#
Abnl. no. of stool	93	80#	87#	80#
Abnormal appetite	87	73#	73#	80#
Nausea	67	53#	67#	67#
Flatulence	73	67#	60#	60#
Vomiting	60	53#	53#	60#
Belching	73	67#	60#	67#
Anorexia	53	60#	60#	60#
Salivation	60	53#	53#	47#
Constipation	33	33#	40#	40#

#p = NS compared to 0 day (before treatment).

Table 5. Group Ib. Effect of BA on Stool microscopic profile (in%)

Parasites & path. Cont.	0 days	15 day	30 day	45 day
G. Cysts	100	87#	80#	80#
G. Tropho.	19	20#	27#	20#
Mucus	100	93#	93#	87#
R.B.Cs	60	53#	53#	60#
Pus cells	73	60#	73#	73#
Fat globules	67	60#	67#	73#
U.F.P.	87	73#	80#	80#
Bacterial outgrowth	60	53#	53#	60#

#p = NS compared to 0 day (before treatment).

Table 6. Group Ib. Effect of BA on Haematological profile (in%)

Parameters	0 days Mean \pm S.E.	15 day Mean \pm S.E.	30 day Mean \pm S.E.	45 day Mean \pm S.E.
Haemoglobin	10.8 \pm 0.4	10.5 \pm 0.4#	10.3 \pm 0.4#	10.6 \pm 0.4#
Eosinophil	9.5 \pm 0.5	9.2 \pm 0.5#	8.7 \pm 0.6#	8.4 \pm 0.6#
Lymphocyte	27.7 \pm 1.4	29.2 \pm 1.2#	31.5 \pm 1.3#	30.9 \pm 1.2#
Monocyte	0.4 \pm 0.2	0.8 \pm 0.1#	0.5 \pm 0.2#	0.6 \pm 0.2#
Polymorph	63.2 \pm 1.3	60.1 \pm 1.2#	61.3 \pm 1.2#	60.7 \pm 1.1#
T.L.C.	8050.2 \pm 50.3	7912.3 \pm 49.5#	8130.5 \pm 52.3#	8002.3 \pm 48.7#

#p = NS compared to 0 day (before treatment).

Table 7. Group Ic. Effect of BA on Clinical profile (in%)

Signs and symptoms	0 days	15 day	30 day	45 day
Diarrhoea	53	0*	0*	0*
Abnl. freq. of stool	73	13*	6*	0*
Foul smelling stool	93	20*	13*	13*
Abnl. consist of stool	73	6*	0*	0*
Abd. discomfort	93	13*	0*	0*
Abnl. no. of stool	80	6*	6*	6*
Abnormal appetite	80	20**	13*	6*
Nausea	67	13*	13*	6*
Flatulence	60	13*	6*	6*
Vomiting	60	6*	0*	0*
Belching	67	20**	13*	13*
Anorexia	60	6*	0*	0*
Salivation	47	6*	13*	6*
Constipation	40	0*	0*	0*

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control.

Table 8. Group Ic. Effect of BA on Stool microscopic profile (in%)

Parasites & path. Cont.	0 days	15 day	30 day	45 day
G. Cysts	80	6*	0*	0*
G. Tropho.	20	0*	0*	0*
Mucus	87	20*	13*	0*
R.B.Cs	60	13*	13*	6*
Pus cells	73	20**	13*	13*
Fat globules	73	13*	6*	6*
U.F.P.	80	20*	20*	13*
Bacterial outgrowth	60	13*	13*	6*

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control group.

Table 9. Group Ic. Effect of BA on Haematological profile (in%)

Parameters	0 days Mean ± S.E.	15 day Mean ± S.E.	30 day Mean ± S.E.	45 day Mean ± S.E.
Haemoglobin	10.6 ± 0.4	11.8 ± 0.3**	12.3 ± 0.3*	13.6 ± 0.3*
Eosinophil	8.4 ± 0.6	4.2 ± 0.3**	3.1 ± 0.2*	2.7 ± 0.2*
Lymphocyte	30.9 ± 1.2	32.2 ± 1.6	30.7 ± 1.2	31.2 ± 1.6
Monocyte	0.6 ± 0.2	0.4 ± 0.1	0.8 ± 0.2	0.5 ± 0.1
Polymorph	60.7 ± 1.1	63.3 ± 1.7	65.3 ± 1.5	64.8 ± 1.4
T.L.C.	8002.3 ± 48.7	8129.2 ± 37.6	7953.6 ± 53.2	8263.6 ± 52.3

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control group.

Table 10. Group Iia. Effect of BA on Clinical profile (in%)

Signs and symptoms	0 days	15 day	30 day	45 day
Diarrhoea	85	0*	0*	0*
Abnl. freq. of stool	92	15*	0*	0*
Foul smelling stool	100	31**	15*	15*
Abnl. consist of stool	100	8*	0*	0*
Abd. discomfort	100	15*	0*	0*
Abnl. no. of stool	100	23*	15*	15*
Abnormal appetite	85	15*	7*	7*
Nausea	100	15*	0*	0*
Flatulence	92	23*	15*	7*
Vomiting	62	7*	0*	0*
Belching	69	15**	7*	7*
Anorexia	31	7*	0*	0*
Salivation	100	23*	15*	15*
Constipation	15	0*	0*	0*

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control.

Table 11. Group IIa. Effect of BA on Stool microscopic profile (in%)

Parasites & path. Cont.	0 days	15 day	30 day	45 day
G. Cysts	100	7*	15*	7*
G. Tropho.	15	0*	0*	0*
Mucus	92	23*	15*	15*
R.B.Cs	69	15*	7*	7*
Pus cells	85	23**	15*	15*
Fat globules	62	7*	15*	7*
U.F.P.	92	31**	23*	23*
Bacterial outgrowth	62	15*	15*	15*

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control.

Table 12. Group IIa. Effect of BA on Haematological profile (in%)

Parameters	0 days Mean ± S.E.	15 day Mean ± S.E.	30 day Mean ± S.E.	45 day Mean ± S.E.
Haemoglobin	7.8 ± 0.5	9.1 ± 0.4**	10.6 ± 0.3*	12.5 ± 0.3*
Eosinophil	10.2 ± 0.6	5.1 ± 0.4**	3.2 ± 0.4*	2.0 ± 0.4*
Lymphocyte	28.8 ± 1.8	31.2 ± 2.2	29.9 ± 2.0	34.5 ± 3.1
Monocyte	0.4 ± 0.4	0.7 ± 0.3	0.8 ± 0.3	0.6 ± 0.3
Polymorph	60.8 ± 3.1	62.3 ± 3.0	66.4 ± 1.7	62.8 ± 3.2
T.L.C.	8147.7 ± 56.2	8423.2 ± 42.8	8239.5 ± 54.2	8349.1 ± 55.2

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control group.

Table 13. Group IIb. Effect of BA on Clinical profile (in%)

Signs and symptoms	0 days	15 day	30 day	45 day
Diarrhoea	60	60#	70#	70#
Abnl. freq. of stool	90	80#	70#	80#
Foul smelling stool	100	80#	90#	90#
Abnl. consist of stool	90	70#	80#	80#
Abd. discomfort	100	80#	70#	70#
Abnl. no. of stool	100	70#	90#	90#
Abnormal appetite	80	60#	70#	80#
Nausea	90	90#	80#	70#
Flatulence	80	90#	80#	80#
Vomiting	50	40#	60#	60#
Belching	60	50#	40#	50#
Anorexia	40	50#	60#	60#
Salivation	100	100#	80#	90#
Constipation	30	30#	20#	20#

#p = NS as compared to 0 day (before treatment)

Table 14. Group IIb. Effect of BA on Stool microscopic profile (in%)

Parasites & path. Cont.	0 days	15 day	30 day	45 day
G. Cysts	100	90#	80#	90#
G. Tropho.	20	10#	10#	20#
Mucus	90	70#	70#	80#
R.B.Cs	60	50#	40#	60#
Pus cells	70	80#	60#	60#
Fat globules	50	40#	40#	50#
U.F.P.	60	60#	50#	40#
Bacterial outgrowth	40	40#	50#	50#

#p = NS as compared to 0 day (before treatment).

Table 15. Group IIb. Effect of BA on Haematological profile (in%)

Parameters	0 days Mean \pm S.E.	15 day Mean \pm S.E.	30 day Mean \pm S.E.	45 day Mean \pm S.E.
Haemoglobin	9.8 \pm 0.2	9.2 \pm 0.3#	9.4 \pm 0.3#	8.9 \pm 0.3#
Eosinophil	10.1 \pm 0.6	9.6 \pm 0.8#	9.3 \pm 0.7#	9.5 \pm 0.7#
Lymphocyte	28.6 \pm 2.1	20.2 \pm 2.9#	30.7 \pm 1.0#	28.2 \pm 2.1#
Monocyte	0.7 \pm 0.3	0.4 \pm 0.7#	0.8 \pm 0.3#	0.6 \pm 0.6#
Polymorph	60.7 \pm 3.2	64.3 \pm 2.8#	59.8 \pm 4.2#	61.3 \pm 3.9#
T.L.C.	8576.2 \pm 52.3	8729.5 \pm 49.2#	8436.0 \pm 56.5#	8589.2 \pm 51.6#

#p = NS as compared to 0 day (before treatment).

Table 16. Group IIc. Effect of BA on Clinical profile (in%)

Signs and symptoms	0 days	15 day	30 day	45 day
Diarrhoea	70	0*	0*	0*
Abnl. freq. of stool	80	20*	10*	0*
Foul smelling stool	90	30**	20*	20*
Abnl. consist of stool	80	20*	10*	10*
Abd. discomfort	70	10*	0*	0*
Abnl. no. of stool	90	20*	20*	10*
Abnormal appetite	80	10*	10*	0*
Nausea	70	20*	10*	10*
Flatulence	80	30**	20*	0*
Vomiting	60	20**	10*	0*
Belching	50	30**	20**	20**
Anorexia	60	30**	20**	10*
Salivation	90	20*	20*	10*
Constipation	20	0*	0*	0*

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control.

Table 17. Group IIc. Effect of BA on Stool microscopic profile (in%)

Parasites & path. Cont.	0 days	15 day	30 day	45 day
G. Cysts	10	0*	0*	0*
G. Tropho.	90	0*	0*	0*
Mucus	80	30**	20*	10*
R.B.Cs	60	20**	10*	0*
Pus cells	60	0*	0*	0*
Fat globules	50	20**	0*	0*
U.F.P.	40	10*	10*	0*
Bacterial outgrowth	50	20*	10*	10*

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control group.

Table 18. Group IIc. Effect of BA on Haematological profile (in%)

Parameters	0 days Mean ± S.E.	15 day Mean ± S.E.	30 day Mean ± S.E.	45 day Mean ± S.E.
Haemoglobin	8.9 ± 0.3	10.3 ± 0.4**	11.6 ± 0.4*	12.5 ± 0.3*
Eosinophil	9.5 ± 0.7	6.2 ± 0.3**	3.4 ± 0.3*	2.3 ± 0.3*
Lymphocyte	28.2 ± 2.1	27.8 ± 2.9	36.5 ± 1.6	33.8 ± 1.9
Monocyte	0.6 ± 0.6	0.9 ± 0.5	0.3 ± 0.6	0.7 ± 0.6
Polymorph	61.3 ± 3.9	65.6 ± 4.5	60.3 ± 3.5	63.1 ± 4.2
T.L.C.	8589.2 ± 51.6	8139.5 ± 45.2	8343.3 ± 44.3	8563.7 ± 46.2

*p<0.01, ** p<0.05 as compared to 0 day (before treatment) and placebo control group.

completed in 69 cases i.e. 21 males, 25 females and 23 children of Giardiasis with significant improvement in all parameters recorded. A comparative study with modern drugs was not thought necessary as the mechanism of action of modern drugs are entirely different. These are usually immunodepressant while herbal drugs act by complex mechanism and are immunomodulatory in nature. All the patients were advised to take boiled water during the period of study and reinfections were not observed. This fact proves this disease to be water borne in the city. Thus the present study indicates large use of BA, an innocuous and cheap herbal preparation in treatment of Giardiasis.

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